Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of foot reflexology massage on pain, anxiety and fatigue in patients undergoing coronary artery bypass surgery

Protocol summary

Summary

Background: Pain and fatigue are complications after coronary artery bypass graft surgery. Because of non-pharmacological methods are the preferred pharmacological agent therefore; the purpose of this study was assessment of effect of foot reflexology on pain and fatigue in patients undergoing CABG. Methods: This study was a randomized controlled clinical trial, conducted on 80 patients hospitalized in the Heart Center of Mazandaran in 2011. Sampling was in manner of Non-random and accessible. Patients were age and sex matched and divided randomly in two equal groups of case and control. The reflexology group received 20-minutes left foot massage, from the second day after surgery for 4 consecutive days. In the control group, patient's left foot without applying any pressure and only for 1 minute was fat. Variables pain and fatigue before and after the intervention was recorded by the use of visual analogue scale at the time mentioned. The findings were analyzed by using the software SPSS version 17, descriptive and inferential statistics and tests of x^2 and Repeated measurments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109067494N1**
Registration date: **2012-05-30, 1391/03/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-05-30, 1391/03/10

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7551

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2011-09-08, 1390/06/17

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on pain, anxiety and fatigue in patients undergoing coronary artery bypass surgery

Public title

The effect of foot reflexology massage on pain, anxiety and fatigue in patients undergoing coronary artery bypass surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: first candidate for open heart surgery (CABG); under non- emergency heart- lung pump.
Exclusion criteria: lack of patient satisfaction on the

ongoing research; lack of consciousness; the need to intra aorta pump; intubation of more than 24 hours; bleeding more than 200 cc per hour of chest tube; Performed surgery to repair or replace the valve with CABG; severe visual impairment; history of chronic pain; alcohol and drug addiction; drug addiction 4 hours before; having fractures; infected wounds and skin diseases in the left leg; severe disorders of hearing and visual; covered the sole of the left foot with dressing; remove the graft from the left foot and left sole are in the presence of any sensory impairment.

Age
From **40 years** old to **78 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, mazandaran, Iran.

City
sari

Postal code
4816715793

Approval date
2011-09-07, 1390/06/16

Ethics committee reference number
90-88

Health conditions studied

1

Description of health condition studied
coronary artery by pass graft

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
Pain after coronary artery bypass graft surgery

Timepoint
The second day, third, fourth and fifth after the surgery and immediately after each intervention.

Method of measurement
Visual Analog Scale

2

Description
Anxiety after coronary artery bypass graft surgery

Timepoint
The second day, third, fourth and fifth after the surgery and immediately after intervention

Method of measurement
Visual Analog scale

3

Description
Fatigue after coronary artery bypass graft surgery

Timepoint
The second day, third, fourth and fifth after the surgery and immediately after each intervention.

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Foot reflexology massage in the case group 20 minutes on the second, third, fourth and fifth after coronary artery bypass graft surgery

Category
Treatment - Other

2

Description
In the control group, only the left foot with fatty cream and researcher was present for 20 minutes on the second day, third, fourth and fifth postoperative coronary artery graft surgery on the patient's bedside

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh zahra hospital
Full name of responsible person
Masoumeh Bagheri Nesami
Street address
Mazandaran University of Medical Sciences, three-way Joibar, highway Basij, Imam square, Sari, mazandaran, Iran.
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Mazandaran University of Medical Science
Full name of responsible person
Dr. Ahmahali Enayati
Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, mazandaran, Iran.
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Mazandaran University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Full name of responsible person
Position
Other areas of specialty/work
Street address
City
Postal code
4815696869
Phone
+98 11 3379 5555
Fax
Email
hedayat2003@yahoo.com
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty